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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/991,143	12/16/97	CONTI-FINE B	600.423US1

HM12/1105
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EXAMINER	
NOLAN, P	
ART UNIT	**PAPER NUMBER**
1644	13

DATE MAILED: 11/05/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/991,143	Conti-Fine
Examiner	**Group Art Unit**
NOLAN	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 8-19-99.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 1- 13, 16-18, 31, 34- 40 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☐ Claim(s)_____ is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

Part III DETAILED ACTION

1. This application is a continuation-in-part of 08/564,972.

2. Claims 1-13, 16-18, 31 and 34-40 are pending.

3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39 and 40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Applicant's arguments and amendments have removed all of the pending rejections.

5. The following new grounds of rejections are necessitated by the amendment filed 8-19-99.

6. Claims 1-13, 16-18, 31 and 34-40 may not have the benefit under ***35 USC § 120*** of the parent filing date (11-30-95), because the claimed methods are not disclosed in the parent applications, serial numbers 08/564,972.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 6, 8-9, 17-18, 31, 34 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hoyne et al. (5).

Hoyne et al., teaches the nasal administration of the dominant T cell epitope of dust mite allergens in mice, wherein said administration decreased antibody production and T cell reactivity in these mice and inhibited a further response from occurring (i.e. tolerization (abstract, Fig 1, Fig 2, in particular). Claims 34 and 37 are included because a decrease in antibody production would inhibit antibody affinity due to less antibody.

The prior art teachings anticipate the claimed invention.

8. Claims 1-5, 8 and 11-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO94/00148. (N).

The '148 patent teaches inhibiting myasthenia gravis by

intranasally administering variants of dominant T cell epitopes to humans wherein the autoreactive T cells and autoantibody production is decreased in said myasthenia gravis patients (pages 10-15, in particular).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 2 and 16 are rejected under 35 U.S.C. § 103 as being unpatentable over Hoyne et al.,(5), in view of Norman (U), of record.

Hoyne et al.,has been discussed supra. In addition, Hoyne et al., teaches that intranasal peptide therapy induces tolerance not only in naive mice but also inhibits the function of T cells previously sensitized to the antigen.

The claimed invention, recited in claim 16 differs from the prior art teaching by the recitation of using a domestic cat allergen. However, Hoyne et al., teaches the use of T cell epitopes from cats to treat humans.

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute subcutaneous injection taught by Norman et al., with intranasal therapy taught by Hoyne et al., because Hoyne et al., teaches that intranasal peptide therapy induces tolerance not only in naive mice but also inhibits the function of T cells previously sensitized to the antigen. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

10. Claims 1, 3, 6, 7, 8, 9, 10, 34, 37 and 38 are rejected under 35 U.S.C. § 103 as being unpatentable over Hoyne et al.,(5), in view of Kurup et al. (U), newly cited.

Hoyne et al.,has been discussed supra. In addition, Hoyne et al., teaches that intranasal peptide therapy induces tolerance not only in naive mice but also inhibits the function of T cells previously sensitized to the antigen.

The claimed invention, recited in claim 7, 10 and 38 differs from the prior art teaching by the recitation of using a fungal allergen. However, Kurup et al., teaches T cell epitopes derived from Aspergillus fumigatas that induce a protective Th1 response (Table 2, in particular) .

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the T cell epitopes derived from Aspergillus fumigatas that induce a protective Th1 response taught by Kurup et al., and use them in the intranasal therapy taught by Hoyne et al., because Hoyne et al., teaches that intranasal peptide therapy induces tolerance not only in naive mice but also inhibits the function of T cells previously sensitized to the antigen. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

11. Claims 34-36 are rejected under 35 U.S.C. § 103 as being unpatentable over Hoyne et al.,(5), in view of U.S. Patent No. 4,649,132, of record.

Hoyne et al.,has been discussed supra. In addition, Hoyne et al., teaches that intranasal peptide therapy induces tolerance not only in naive mice but also inhibits the function of T cells previously sensitized to the antigen.

The claimed invention differs from the prior art teaching by

the recitation of using an endogenous antigen that inhibits or reduces the affinity of the antibody for an antigen. However, the '132 patent teaches the epitopes derived from Factor VIII, that are recognized by autoantibodies in the sera of patients who are hemophiliacs (columns 1-5 in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the autoantibody Factor VIII epitopes taught by the '132 patent, and use them in the intranasal therapy taught by Hoyne et al., because Hoyne et al., teaches that intranasal peptide therapy induces tolerance not only in naive mice but also inhibits the function of T cells previously sensitized to the antigen. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 to 4:30.

14. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939.

Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
November 1, 1999

Christina Chan
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